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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.  | CONFIRMATION NO. |
|--|-------------|----------------------|----------------------|------------------|
| 10/563,011   | 06/19/2006  | Beatrice Schaack     | 284025US0XPCT        | 8486             |
| 22850  | 7590        | 09/25/2007           | EXAMINER             |                  |
| OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C.<br>1940 DUKE STREET<br>ALEXANDRIA, VA 22314 |             |                      | VIVLEMORE, TRACY ANN |                  |
|  |             |                      | ART UNIT             | PAPER NUMBER     |
|  |             |                      | 1635                 |                  |
|  |             |                      | NOTIFICATION DATE    | DELIVERY MODE    |
|  |             |                      | 09/25/2007           | ELECTRONIC       |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com  
oblonpat@oblon.com  
jgardner@oblon.com

|                              |                                      |                                       |  |
|------------------------------|--------------------------------------|---------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/563,011 | <b>Applicant(s)</b><br>SCHAACK ET AL. |  |
|                              | <b>Examiner</b><br>Tracy Vivemore    | <b>Art Unit</b><br>1635               |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 30 December 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-26 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Election/Restrictions*

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-15, 17-21, 24 and 25, drawn to double stranded oligonucleotides targeted to the  $\alpha$ ,  $\alpha'$  or  $\beta$  subunit of mouse CK2 protein kinase. Election of this invention requires a further election of a single nucleotide sequence as set forth below.

Group 2, claim(s) 1-15, 17-21, 24 and 25, drawn to double stranded oligonucleotides targeted to the  $\alpha$ ,  $\alpha'$  or  $\beta$  subunit of human CK2 protein kinase. Election of this invention requires a further election of a single nucleotide sequence as set forth below.

Group 3, claim(s) 16, drawn to a transgenic nonhuman animal comprising the precursor of claim 11 as it reads on mouse CK2 protein kinase.

Group 4, claim(s) 16, drawn to a transgenic nonhuman animal comprising the precursor of claim 11 as it reads on human CK2 protein kinase.

Group 5, claim(s) 22-23, drawn to use of an oligonucleotide of claims 1, 11 or 14 as they read on mouse CK2 protein kinase for preparing a medicinal product for use in prevention or treatment of cancer.

Group 6, claim(s) 22-23, drawn to use of an oligonucleotide of claims 1, 11 or 14 as they read on human CK2 protein kinase for preparing a medicinal product for use in prevention or treatment of cancer.

Group 7, claim(s) 26, drawn to use of an oligonucleotide of claim 1 for screening for molecules capable of modulating the activity of the  $\alpha$ ,  $\alpha'$  or  $\beta$  subunit of mouse CK2 protein kinase.

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Group 8, claim(s) 26, drawn to use of an oligonucleotide of claim 1 for screening for molecules capable of modulating the activity of the  $\alpha$ ,  $\alpha'$  or  $\beta$  subunit of human CK2 protein kinase.

The inventions listed as Groups 1-8 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: groups 1, 3, 5, and 7 do not share a special technical feature with groups 2, 4, 6 and 8 because groups 1, 3, 5 and 7 are directed to compounds and methods related to RNAs targeted to a mouse gene while groups 2, 4, 6 and 8 are directed to RNAs targeted to a human gene.

Additionally, the special technical feature of groups 2, 4, 6 and 8, oligonucleotides targeted to human CK2, does not make a contribution over the prior art, as evidenced by Ulloa et al. (of record), who disclose antisense oligonucleotides targeted to CK2.

The special technical feature of groups 1, 3, 5 and 7 also does not make a contribution over the prior art because it lacks an inventive step. Based on the teachings of Orlandini et al. regarding the oncogenic potential of the mouse CK2  $\alpha'$  subunit via the relationship with fibroblast cell transformation, and the teachings of Elbashir et al. (of record) of the superior gene silencing properties of siRNAs, the invention of double stranded oligonucleotides targeted to CK2 lacks an inventive step.

***Restriction to a single nucleotide sequence***

According to the guidelines in Section (f)(i)(a) of Annex B of the PCT Administrative Instructions, the special technical feature as defined by PCT Rule 13.2 shall be considered to be met when all the alternatives of a Markush-group are of similar nature. For chemical alternatives, such as the claimed polynucleotide sequences, the Markush group shall be regarded as being of similar nature when:

- (A) all alternatives have a common property or activity and
- (B)(1) a common structure is present, i.e., a significant structure is shared by all of the alternatives or
- (B)(2) in cases where the common structure cannot be the unifying criteria, all alternatives belong to an art recognized class of compounds in the art to which the invention pertains.

The instant CK2 protein kinase sense strand sequences are considered to be each separate inventions for the following reasons:

The sequences do not meet the criteria of (A), common property or activity or (B)(2), art recognized class of compounds. Although the sense strand sequences of the instant application all target and modulate expression of the same gene, each sequence behaves in a different way in the context of the claimed invention. Each sequence targets a different and specific region of one of the subunits of mouse or human CK2 protein kinase. Each member of the class cannot be substituted; one for the other, with the expectation that the same intended result would be achieved.

Further, although the instant sequences target the same gene, the sequences do not meet the criteria of (B)(1), as they do not share, one with another, a common core structure due to their unique nucleotide sequences. Accordingly, unity of invention between the CK2 protein kinase sense strand sequences of the instant application is lacking and each sequence claimed is considered to constitute a special technical feature.

If either of invention 1 or invention 2 is elected, applicant must further elect a single sequence from those listed in claim 2 that corresponds to the elected target (mouse or human) for examination. This election will be considered a constructive election of the corresponding region in claim 1 and this corresponding region should be clearly identified in the response to the restriction requirement.

***Advisory information regarding claim 1***

The reference to accession numbers to identify gene sequences has been noted in this application. Such references are likely to result in a rejection under 35 USC 112, second paragraph, therefore in the interests of compact prosecution, applicants are advised that such references should be made by reference to a SEQ ID NO and a formal sequence listing in compliance with the provisions of 37 CFR 1.821-1825.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the

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requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tracy Vivlemore whose telephone number is 571-272-2914. The examiner can normally be reached on Mon-Fri 8:30-5:00.

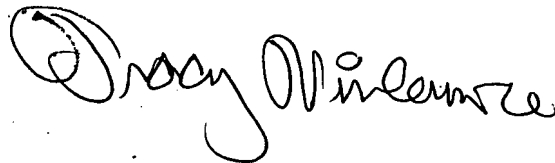
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, J. Douglas Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Tracy Vivlemore  
Examiner  
Art Unit 1635

TV  
September 18, 2007

A handwritten signature in black ink, appearing to read "Tracy Vivlemore", is written over the typed name and title.